K062883

GEREONICS, INC.

244 La Barranca Drive
Solana Beach, California 92075
Telephone: 1-800-654-6266 Fax: (858) 481-3654

510(k) Summary:

Date: May 7, 2007

Submitter:

Gereonics, Inc.
244 La Barranca Drive
Solana Beach, CA 92075
Contact Person: Gerald A. Rost
Tel: 760 728-4640 Fax: 760 728-4640

JUN 1 3 2007

Device Identification:

Proprietary Name: Gereonics Ultra-Piezo Limb Movement Sensor
Classification Name: Monitor, Breathing Frequency
Device Classification: II
Regulation Number: 868.2375
Product Code: BZQ

Predicate device is:

PLM SENSOR – 510(k) Number K940014
Pro-Tech Services, Inc.
4338 Harbour Pointe Blvd., Mukilteo, WA 98275

Device Description:

The Pro-Tech predicate device and the Gereonics Ultra-Piezo Limb Movement Sensor (LMS) utilize a piezo disc (sometimes referred to as a piezo element, diaphragm or bender). There is no external voltage supply -- the sensor directly converts motion to voltage. The piezo disc and output resistor convert minute taps to voltage. A lengthy lead wire extends from this assembly and terminates with two electrode style safety connectors.

The LMS is applied to the patients limb using 3M Coban LF Latex Free Self-Adherent Wrap. The sensor is reusable and the self-adherent wrap is disposable. The predicate device is applied using a reusable Velcro strap with a pouch that holds the LMS.

Intended Use:

For adult use. The Gereonics Ultra-Piezo Limb Movement Sensor (LMS) is used to detect periodic limb movements for recording or monitoring on a physiological amplifier. The LMS is intended for use in sleep disorders studies.

Information Supportive of Substantially Equivalent Claim:

Features	Gereonics	Pro-Tech
Piezo disc sensor – 12mm diameter	Yes	Yes
Built-in passive output chip resistor	Yes – 50K (at sensor)	Yes – 75K (at sensor)
Termination of about 11 foot cable with DIN 45-802 Safety Connectors	Yes	Yes
Connects to physiological recorder	Yes	Yes
Comparable voltage output on test fixture	Yes	Yes
Completely passive system No batteries or power supply	Yes	Yes
Body attachment method	Self-Adherent Wrap (Tape)	Velcro Strap and Pouch
For Sleep Disorders testing	Yes	Yes

Electrically, the devices are nearly identical and very simple. There is a piezo disc, a chip resistor, a 11 foot lead wire terminated with safety connectors and three solder points. The chip resistor value was modified to reduce noise. The sensors are encapsulated differently. The essential difference is the method of attachment to the patient's body -- Pro-Tech uses a Velcro strap and pouch arrangement and the Gereonics device uses 3M Coban LF latex free self-adherent wrap.

Data Supportive of Substantially Equivalent Claim:

Bench tests were conducted on the Pro-Tech predicate device and the Gereonics LMS for comparative performance test and comparative temperature test.

Comparative Performance Test:

The performance tests as performed on the Gereonics Test System show that the sensitivity to a controlled tapping device is very similar. The Pro-Tech test unit yielded a peak to peak voltage output of 300 millivolts compared with the Gereonics 600 millivolts. This is within the normal variability of other test devices at Gereonics. The output pulse waveform is identical on the test system, except for amplitude.

The sensors were also attached to the ankle using 3M Coban LF latex free self-adherent wrap and tested for sensitivity by lightly tapping the foot on the floor. The signal waveform and sensitivity were identical.

Comparative Temperature Test:

Both devices were tested across the temperature range of 8°C to 43°C. Both performed similarly. The Pro-Tech temperature coefficient was about -5% per °C and Gereonics -6% per°C in the typically used range of 20 to 30°C.

Conclusions:

The electrical design of the Gereonics LMS is essentially identical to the predicate Pro-Tech device with the exception of output resistor value.

The performance as tested on the Gereonics tapping test system is very similar for both devices with identical pulse waveforms. Waveform height (sensitivity) varies somewhat between devices but can readily be accommodated by bioamplifier gain controls.

The performance of both devices was identical when attached to the ankle and tested by small repetitive taps on the floor.

The devices are encapsulated differently but perform similarly.

Gerald Rost Gerald Rost

Date: May 7, 2007

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Gerald A. Rost
Manager
Gereonics, Incorporated
244 La Barranca Drive
Solana Beach, California 92075

JUN 13 2007

Re: K062883
Trade/Device Name: Gereonics Ultra-Piezo Limb Movement Sensor
Regulation Number: 21 CFR 868.2375
Regulation Name: Breathing Frequency Monitor
Regulatory Class: II
Product Code: BZQ
Dated: May 19, 2007
Received: May 22, 2007

Dear Mr. Rost:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

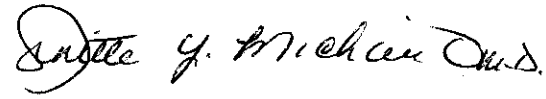
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K062883

Device Name: Gereonics Ultra-Piezo Limb Movement Sensor

INDICATIONS FOR USE:

For adult use.

The Gereonics Ultra-Piezo Limb Movement Sensor (LMS) is used to detect periodic limb movements for recording or monitoring on a physiological amplifier. The LMS is intended for use in sleep disorders studies.

CAUTION:

This product is for diagnostic purposes only and is not to be used in a life-sustaining circumstance. Federal law restricts this device to sale by or on the order of a Physician.

WARNING:

The sensor should not be immersed in fluids.

Prescription Use __X__ AND/OR Over-The-Counter-Use _____
(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

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